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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/966,036	HAPP, DORRIE M.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,7,10,14,15,17,19,21,23,27,28,34,39-46,50 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,7,10,14, 15, 17,19,21,23,27, 28,34,39-46,50 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 10/18/2007. Claims 16, 29, 32, 37, 47 and 53-64 are canceled. Claims 2, 4, 7, 10, 14, 15, 17, 19, 23, 27, 28, 34, 39-41, 44, 46, 50 and 52, are amended. Claims 2, 4, 7, 10, 14, 15, 17, 19, 21, 23, 27, 28, 34, 39-46, 50 and 52 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 4, 7, 10, 14, 15, 17, 19, 21, 23, 27, 28, 34, 39-46, 50 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter.

The specification as filed does not envision a layer comprising drug and polymer that is supported by the surface of the stent.

Applicant refers to Figures 2A-2E as providing support for the new limitation the layer comprising the drug and polymer is supported by the surface of the stent. However, the Figures 2A-2E depict a primer layer between the stent and the layer containing the drug and the polymer. Applicant further refers to page 8, lines 17-21 as providing support for the layer comprising the drug and polymer to be supported by the surface of the stent. Specifically, the section referred to by applicant states that:

> The coating comprises a coating applied on the surface of the stent. The coating according to embodiments of this invention optionally includes a polymer primer layer applied directly on the surface of the stent, a drug-polymer layer disposed on top of the primer polymer layer, and optionally a topcoat polymer layer applied on top of the drug-polymer layer.

The section does not state that the layer containing the polymer and drug is on the surface of the stent. Therefore, the recitation of a first layer including "a drug and polymer supported by a surface of the stent" is new matter and was not envisioned at the time the application was filed.

Applicant may overcome this rejection by removing the new matter from all the claims.

4. Claims 2, 4, 7, 10, 14, 15, 17, 19, 21, 23, 27, 28, 34, 39-46, 50 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims say layer comprising a polymer and a drug is supported by the surface of the stent and it is unclear what is intended by the "supported by a surface of the stent."

The "supported by a surface of the stent" is taken to mean that the stent comprises a layer that contains polymer and an active agent for examination purposes.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 4, 7, 10, 14, 15, 17, 21, 23, 27, 28, 34, 39-46, 50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (US 6,663,662 B2).

Pacetti teaches prosthesis that can be a balloon-expandable stent or self-expandable stent (abstract; column 2, lines 50 and 51) that is coated with primer/tie/adhesive/intermediary layer that is a third composition (column 3, lines 12-15; column 7, lines 64-67; column 8, lines 1, 2, 14) with the primer/tie/adhesive/intermediary layer comprised of polymer (Table 1; column 16, lines 46-49), a second composition or layer comprised of active agent/drug and polymer (column 3, lines 7-11) with active agent including any one of the agents listed in column 10, line 63 to column 11, line 39 and actinomycin D specifically named as antiproliferative substance (column 11, lines 4-11), and a first composition that is comprised of particles (column 2, lines 48, 65-67) with the particles made form any suitable organic materials or inorganic materials such as carbon black, titanium nitride and polymeric materials (column 3, lines 14-17, 23-29, 31-67). The actinomycin D meets the limitation of light sensitive drug; the carbon black meets the limitation of the UV-protective compound and the first, second and third layers meet the requirements for the layers. Pacetti does not refer to the particles such as the metal particles as UV protecting but because same product would have same properties, the carbon black when used as the particles would also confer light protection for the active agent. The diffusion barrier is 0.1-10 micron

(column 18, lines 62-64; column 19, lines 1-5) with the thickness meeting the requirements of claims 42 and 43. The layers recited in claims 2, 4, 7, 10, 14, 34, 39-41, 44, 50 and 52 read on the layers of Pacetti and the medical devices (stent) described by these claims also read on the medical device of Pacetti. Pacetti coats the stent so that method claims 15, 19, 28 and 46 are met. While Pacetti describes how much active agent should be present in the coated stent (column 8, lines 65 and 66), Pacetti does not describe the ratio of the particles to the polymer. But the artisan is able to use appropriate amount of the particles in the coating composition or in relation to the polymer in the coating composition. Therefore, it would have been obvious to one of ordinary skill in the art to coat the a stent with first, second and third compositions and where the artisan has good reason to use specific amounts of the particle and polymer and active agents to achieve controlled/sustained release of the active agent from the stent.

7. Claims 2, 7, 10, 14, 34, 39-41, 44, 50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanikanti et al. (US 5,900,425) in view of Sinclair et al. (US 5,760,118) and further in view of Yan (US 6,240,616).

Kanikanti teaches solid dosage composition comprising light sensitive active agents and a light protective coating (column 4, lines 7-14). The light sensitive active agent or drug is prepared with a polymer to obtain controlled release of the active agent or drug (column 2, lines 23-35, 52-67; column 3, lines 26-46), and this meets the limitation of the first layer in the generic claims. Kanikanti states that for "light sensitive active compounds, such as nifedipine and nimodipine, the controlled release tablets must then be provided with light protective coating in order that the active compound is not degraded by light." In Kanikanti, the coating is done with HPMC film forming polymer, PEG plasticizer and titanium oxide and iron oxide light scattering

and absorbing pigments (column 4, lines 6-14). The disclosure of the protective coating meets the limitation of the second layer containing protective compounds in the generic claims.

The light sensitive drug as recited in claims reads on the light sensitive drug, nifedipine and nimodipine disclosed by Kanikanti. The protective coating layer of Kanikanti does not have a drug or active agent and Kanikanti thus meets the limitation of the second layer. In the absence of factual evidence, the ratio between the drug, the compound, and the drug recited in claims is not inventive over the prior art composition.

While Kanikanti discloses using titanium dioxide and iron oxide as protective compounds, Kanikanti does not disclose the use of carbon black or titanium-nitride-oxide. However, Sinclair teaches that carbon black, zinc oxide and substituted benzophenones are UV-light absorbers which when added to a composition make the composition more resistant to degradation by ultraviolet radiation (column 31, line 67 to column 32, line 4).

Regarding the ratio of the light or UV protecting compound, it is noted that there is no demonstration in applicant's specification showing that certain amount of the light or UV-protective compound relative to certain amount of the polymer in the top-coating composition (recited ratios) provides unusual results to the coated medical device. For example, the specification at paragraph [0053] of the published application, states "the ratio, by mass, of the light- and/or UV-radiation protective compound to the polymer is between about 3 to 1 (at the lower range of concentrations of the solution to be sprayed) and about 1 to 3 (at the higher range)" without further description of what if any unexpected/unusual results from the cited ratio provides to the device.

Kanikanti in view of Sinclair teach layered composition/product having titanium dioxide or iron oxide or carbon black as protective compounds. The combination of Kanikanti and Sinclair discloses the delivery of drugs such as nifedipine or nimodipine or notrendipine or nisodipine or felodipine or nicardipine as described above. Nifedipine and nimodipine of Kanikanti meets the limitation of light sensitive drug. The delivery device of the combination of Kanikanti and Sinclair is not a stent as is recited in the amended claims. However, it is known in the art that several drugs such as nifedipine (Yan at column 4, lines 38, 39 and 56) are delivered to target site by means of stent that is coated with therapeutic agent (column 5, lines 38-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the light protective compound of Kanikanti or that of Sinclair in the composition of Kanikanti with the expectation that in either case, the light protective coating would protect the light sensitive drugs/active agents of Kanikanti from being degraded by that UV-light and to deliver the combined composition of Kanikanti and Sinclair with a stent according to Yan with the expectation of delivering the active agent to the target site.

8. Claims 15, 17, 19, 21, 23, 27, 28, 42, 43, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanikanti et al. (US 5,900,425) in view of Sinclair et al. (US 5,760,118) and further in view of Yan (US 6,240,616).

Kanikanti and Sinclair in view of Yan are discussed above as rendering the product claims 2, 7, 10, 14, 34, 39-41, 44, 50 and 52 obvious. The combined prior art discloses the delivery of drugs such as nifedipine or nimodipine or notrendipine or nisodipine or felodipine or nicardipine, which meets the limitation of light sensitive drug. Kanikanti teaches first and second coating layers. The Kanikanti process is a process of coating a tablet with light

protective layer broadly meets the requirement for coating a medical device. But the device of the combined reference of Kanikanti and Sinclair is not a stent.

However, it is known in the art that several drugs such as nifedipine (Yan at column 4, lines 38, 39 and 56) are delivered to target site by means of stent that is coated with therapeutic agent (column 5, lines 38-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the light protective compound of Kanikanti or that of Sinclair in the composition of Kanikanti to coat a medical device with the expectation that in either case, the light protective coating would protect the light sensitive drugs/active agents of Kanikanti from being degraded by that UV-light and be motivated to coat a stent with the combined composition of Kanikanti and Sinclair according to Yan in order to deliver the combined composition of Kanikanti and Sinclair to the target site.

Response to Arguments

9. Applicant's arguments filed 10/18/07 have been fully considered but they are not persuasive.

Applicant argues that Yan cannot be combined with Kanikanti and Sinclair because Kanikanti discloses orally administrable solid, stable pharmaceutical composition, while Yan discloses medicated prosthesis such as a stent and that modification of Kanikanti would change the principle of the operation.

Response:

The purpose of Kanikanti is to deliver light sensitive drugs such as Nifedipine and nimodipine by means of coated oral dosage form with the various layers providing delay in the release of the active agents. In the same way, the coated stent of Yan delivers nifedipine to the

desired site. Thus, nifedipine can either be delivered orally or via a stent with the stent having the advantage of delivering the nifedipine to the desired site. There is therefore, no change in the principle of operation, which in this case is the delivery of drugs such as nifedipine using a layered delivery device and the principle in both cases is to sustainably deliver nifedipine.

No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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